



- ▶ Triad Disposables
- ▶ Triad Pharmaceuticals

August 20, 2001

0597 '01 AUG 23 P1:42

Dr. Charles Ganley, M.D.  
Division of Over the Counter Drugs  
Office of Drug Evaluation

Dockets Management Branch (HFA-305)  
Docket No. 78N-036L  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

We have reviewed our files for sodium phosphate enema and did not find any reports of serious adverse drug reactions per the definitions provided in 21 CFR section 310.305 (b) for the past ten (1991-2001) years. Please contact us if we can be of further assistance.

Very Truly Yours,

Frances Lee  
Director, Quality Assurance

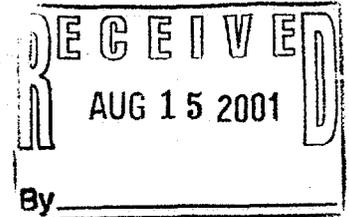
Cc: Dave Haertle

78N-036L

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- ▶ *Triad Disposables*
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August 7, 2001

155-8 201 Aug 23 11:29

Charles J. Ganley, M.D.  
Director  
Division of Over-the-Counter Drug Products  
Office of Drug Evaluation V  
Center for Drug Evaluation and Research  
FDA  
5630 Fishers Lane  
Rockville, MD 20852

RE: Docket No. 78N-036L

Dear Charles,

We received your request for copies of all serious adverse drug experience reports associated with Sodium Phosphate Enemas received over the past 10 years. We are searching our files and will provide these reports no later than September 17, 2001. Please contact us if you have any problems with this date.

Very Truly Yours,



Frances Lee  
Director, Quality Assurance

Cc: Dave Haertle

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE:

9/20/01

FROM:

Director

Division of OTC Drug Products, HFD-560

SUBJECT:

Material for Docket No. 78N-036L

TO:

Dockets Management Branch, HFA-305

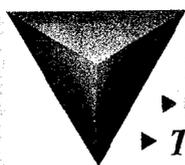
The attached material should be placed on public display under the above referenced Docket No.

This material should be cross-referenced to Comment No. \_\_\_\_\_



Charles J. Ganley, M.D.

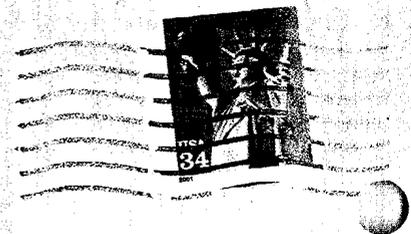
Attachment



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- ▶ Triad Pharmaceuticals

19355 Janacek Court Brookfield, WI 53045



Dr. Charles Gahley, M.D.  
Division of Over the Counter Drugs  
Dockets Management Branch (HFA305)  
Docket No. T8N-036L  
F.D.A.  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852